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In the Supreme Court of the United States

OCTOBER TERM, 1984

LEE M. THOMAS, ACTING ADMINISTRATOR,
UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY,
Appellant,

vs.

UNION CARBIDE AGRICULTURAL PRODUCTS
COMPANY, INC., ET AL.,
Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF OF AMICUS CURIAE GULF AND GREAT PLAINS LEGAL FOUNDATION IN SUPPORT OF APPELLEES

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INTEREST OF AMICUS CURIAE

Amicus Gulf and Great Plains Legal Foundation is a not-for-profit public interest legal foundation established in 1976. Its goals include the preservation of the free enterprise system and the protection of liberty and property rights of citizens.

Headquartered in Kansas City, Missouri, Gulf and Great Plains Legal Foundation is in the middle of America's agricultural region. Innovative and effective technology in the pesticide industry is vital to agricultural productivity. The Foundation has represented farmers in cases of concern to the agricultural community and has

represented the interests of consumers of agricultural products.

As well, Gulf and Great Plains Legal Foundation has a continuing interest in issues affecting the chemical industry and has submitted comments before federal agencies and appeared as amicus curiae in cases raising issues of concern to the industry. The Foundation has appeared as amicus curiae before this Court in a number of cases involving a broad range of public interest issues.

The purpose of amicus in submitting this brief is not to reiterate the constitutional arguments advanced in Appellees' Brief. Rather, this Amicus Brief is submitted to show the economics involved in producing a successful pesticide and the potential effects the present compensation system could have on innovation within the industry.

SUMMARY OF ARGUMENT

The pesticide business is a highly regulated industry in the United States. The major piece of legislation affecting those companies involved in developing and producing pesticides in the United States is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). 7 U.S.C.A. 136-136y (West 1980 & West Supp. 1984). The question facing this Court is whether the FIFRA compensation system set forth at 7 U.S.C. §136a(c)(1)(D) is constitutional when that system provides no standards for determining the appropriate amount of compensation and provides virtually no judicial review of the compensation decision.

Gulf and Great Plains Legal Foundation is concerned about the effect this compensation system could have on innovation in the pesticide industry. Pesticide producers are engaged in a high risk business. Each year, companies spend millions of dollars on research and development of new pesticides. Thousands of compounds are tested but very few are commercially successful. The few that are successful must support the years of research and development necessary to produce a commercially viable pesticide.

Obtaining the data necessary to support EPA registration greatly adds to research and development expenditures both in terms of time and money. Regardless of the great investment, it is this information that is subject to forced sale under FIFRA. Release of such information to competitors could destroy the commercial success of a product. Competitors who purchased the data would be given in shortcut to the pesticide market without incurring the great expense of time and money to orginally develop the data.

FIFRA has had and will have an impact on the overall availability of pesticides. The present statutory protections afforded product developers by both FIFRA's "exclusive use" provisions and by the patent law are not sufficient to protect the considerable investment in research and development. Clear standards must be set forth to guide the determination of compensation for data submitted under FIFRA. As well, opportunity for meaningful judicial review of the compensation decision must be required. If such safeguards are not incorporated, incentives for the industry to devote resources to research and development will be severely curtailed and innovation in the industry will suffer.

ARGUMENT

I

THE PESTICIDE INDUSTRY IS AN EXTREMELY HIGH RISK ENTERPRISE INVOLVING LONG TERM INVESTMENT IN RESEARCH AND DEVELOPMENT AMOUNTING TO MILLIONS OF DOLLARS ANNUALLY.

The pesticide industry is an important industry in this country. Thousands of companies are engaged at some level or another in the production and marketing of pesticides. Most of these companies are engaged in the manufacture of end-use or formulated products containing an identical or similar "active ingredient" combined with similar "inert ingredients" to dilute, dissolve, stablilize or otherwise improve the performance of the final product. There are approximately 400 producers of basic pesticidal chemicals or "active ingredients", in the United States, of which approximately ten percent engage in the development of new products. The basic pesticidal chemicals are generally pure forms of active ingredients used to produce final formulated products. Basic manufacturers generally undertake the costly and time consuming testing to establish the risk and benefit characteristics of the chemicals that are the basic ingredients for all pesticides. S. Rep. No. 334, 95th Cong., 1st Sess. 27 (1977). Total sales of pesticides can amount to billions of dollars a year. Sales of pesticide chemicals in 1975, for example, were over $2.16 billion at manufacturers' value. Gannon, *FIFRA and the "Taking" of Trade Secrets*, 8 B.C. Envtl. Aff. L. Rev. 593, n.3 (1980); S. Rep. 334, 95th Cong., 1st. Sess. 62-63 (1977).

Research and development of commercially viable pesticides requires expenditure of millions of dollars annually. According to an industry survey in 1975 in which 37 companies reported, $160.5 million were spent for research and development costs. S. Rep. No. 334, 95th Cong., 1st Sess. 62 (1977). It is estimated that an individual company must commit to the expenditure of $5 million to $15 million annually for several years before it will develop a potential commercial pesticide candidate. *Monsanto v. Acting Administrator,* 564 F. Supp. 552, 555 (E.D. Mo. 1983).

In making the decision to enter the pesticide market, company management must realize that a particular product will not make a profit for at least twenty years. Joint Appendix at 130, *Ruckelshaus v. Monsanto,* 467 U.S. ....., 104 S.Ct. 2862 (1984) [hereinafter, *Monsanto* Joint Appendix]. Initially, a problem of sufficient magnitude as to warrant the tremendous amount of time and energy necessary to create and market a solution must be identified. *Id.* Market surveys must be conducted to estimate the number of potential buyers for the product to be developed. If the company is inaccurate in its assessment of the marketplace, millions of dollars could be spent in development of a product that is a technical success, but a commercial failure. *Id.*, p. 136.

Additionally, a problem must be identified that will still be a problem in twenty years. This is necessary because it could take twenty years to solve the problem and get a pesticide on the market. To solve the problem, millions of dollars will be spent annually on scientific personnel, facilities, and sophisticated equipment. *Monsanto v. Acting Administrator,* 564 F. Supp. 552, 555 (E.D. Mo. 1983); *Monsanto* Joint Appendix at 131.

Thousands of compounds will then be screened each year. Most companies examine between 3,000 to 8,000 compounds annually. *Monsanto* Joint Appendix p. 134. The compounds must be narrowed down to those most likely to succeed and then resources devoted to the search for the single best compound. This is an area of great risk—research dollars could be spent in vain if a near miss is chosen rather than a commercial hit. *Monsanto* Joint Appendix at 134, 135.

Once a product is chosen, the process of gathering data for EPA registration is begun. Only registered pesticides may be produced, distributed, sold, or used in the United States. 7 U.S.C.A. §136a (West 1980 and West Supp. 1984). The present registration system forces a product down an expensive path from discovery to marketability. *See* McGarity and Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies,* 93 Harv. L. Rev. 837 (1980) [hereinafter cited as McGarity and Shapiro]. The registration process imposes costs by requiring the company to submit data in support of EPA product registration. S. Rep. No. 334, 95th Cong., 1st Sess. 30-34 (1977). Development of data required to support initial registration of each successfully marketed pesticide may typically cost in excess of $23 million. *Ruckelshaus v. Monsanto,* 467 U.S. ....., 104 S.Ct. 2862, 2871 (1984). A 1976 industry survey found that ten percent of industry outlays for research and development went solely to support registration of products with EPA. National Agricultural Chemicals Association Survey, April 14, 1976, *reprinted in* S. Rep. 334, 95th Cong., 1st Sess. 62 (1977).

It has been conservatively estimated that preparation of the toxicology reports necessary for registration could take between forty-eight and fifty-six months to complete.

This estimate is conservative because it assumes no delays, total efficiency, and a scientific team devoted solely to the task of preparing the reports. Many unforseen circumstances could extend the process. *Monsanto* Joint Appendix at 134, 135.

Time is virtually everything in the pesticide industry. It is the key to profitability. *Monsanto* Joint Appendix at 153. From the time a company first develops a product, it can take six to eight years to obtain registration. *Id.* at 138. Even after the discovery, development and registration process is complete, there may be no immediate return on investment. The fact that a pesticide is placed on the market, does not insure its success. If the toxicology is not right, the product fails. If the toxicology is good but the cost is not competitive, the product fails. If the production is not consistent, there will be no repeat buyers and the product will fail. *Id.* at 135, 136.

Assuming a company manages to create a product with good toxicology and consistent production at a fair price, there is still a lag-time before profits are realized. Substantial profits are not realized until the product penetrates the market. Pesticides usually reach their peak of profitability twelve to twenty years after introduction to the market. *Id.* at 153.

Obviously, there are many variables that can affect the success of a pesticide. Industry statistics show that only one out of 20,000 compounds is successfully marketed. *Id.* at 132. For highly successful compounds, the number tested could be significantly increased. To illustrate, Monsanto's highly successful product, Lasso, was compound number 59,144. Baker's Sencor was 94,337—meaning the company had synthesized and screened 94,337 compounds for a product before they hit on Sencor. *Id.* at 132.

The costs of supporting this process of research and development are enormous. One major producer estimated that up to $80 million annually were spent by the company alone for research and development of agricultural chemicals. *Id.* at 133. It is true that there is a large investment return on successful pesticides. But the one successful pesticide must pay for the thousands of losers developed in the discovery process. S. Rep. No. 334, 95th Cong., 1st Sess. 36 (1977). The financial success of most major pesticide companies rests on profits produced by a very limited number of commercially successful products. In 1975, only twelve products accounted for 40% of the value of pesticide sales. Forty-five products accounted for 70% of total sales. S. Rep. No. 334, 95th Cong., 1st Sess. 60 (1977). Because of the great investment of time and money placed in development of one product, the success of that product is vital to the success of the investing company. Unfortunately, the present FIFRA compensation scheme provides little protection to the investment necessary for successful pesticide production.

II

STATUTORY PROTECTION OF TRADE SECRET INFORMATION IN THE PATENT LAW AND FIFRA'S "EXCLUSIVE USE" PROVISIONS ARE NOT SUFFICIENT TO PROTECT THE ENORMOUS LONG TERM INVESTMENT IN RESEARCH AND DEVELOPMENT.

Since the federal government first began regulating the chemical industry, there have been ever-increasing compliance requirements. With increased requirements come increases in the amount of data required to prove compliance. The data presently required to be submitted in support of EPA registration often contain trade secret

information concerning formulas, test methods and results. As discussed in Section I, obtaining this information is very costly both in terms of time and resources. FIFRA was enacted in 1947, and has been amended on three occasions—in 1972, 1975 and 1978. Each amendment has gradually diminished the protection given to data submitted in support of product registration. *See* Gannon, *FIFRA and the "Taking" of Trade Secrets,* 8 B.C. Envtl. Aff. L. Rev. 593-595 (1980).

The most recent amendment to FIFRA, the Federal Pesticide Act of 1978, has produced several changes that directly affect developers of new pesticides. Pub. L. No. 95-396, 92 Stat. 819 (1978). First, the 1978 amendments took away the ability of developers to label sensitive information as "trade secrets" and thus prevent it from being used or disclosed. Data developers can no longer prevent competitors from using the information that took them many years and millions of dollars to create.

Second, the 1978 amendments created three categories of submitted test data. The first category provides that data submitted in support of an application for a new active ingredient or new use of a pesticide, which is registered after September 30, 1978, is protected by a 10-year period of "exclusive use". Under former law, as written and construed, the "exclusive use" provisions applied not only to trade secret information such as the formula for new active ingredients, but also applied to the test data marked as secret and submitted to the EPA in support of registration. Pub. L. No. 92-516, 86 Stat. 973 (1972) [hereinafter cited as 1972 amendments]; *Chevron Chemical Co. v. Costle,* 443 F. Supp. 1024, 1026 (N.D. Cal. 1978); *Dow Chemical Co. v. Costle,* 464 F. Supp. 395, 398 (N.D. Mich. 1978); *Mobay Chemical Corp. v. Costle,* 447 F. Supp. 811,

824-27 (W.D. Mo. 1978). Limiting the "exclusive use" provisions to new active ingredients and new uses results in considerable restriction of the protection formerly afforded by the 1972 and 1975 amendments. The second category provides that any data submitted on or after January 1, 1970, may be used in support of another application within a 15-year period following submission of the data, but only if the applicant has offered to compensate the original data submitters. This provision applies to all data not qualifying for the ten-year "exclusive use" provision. The third category created by the 1978 FIFRA amendments concerns data for which periods of "exclusive use" or compensated use have expired. This data may be freely considered by EPA in support of any other application. 7 U.S.C.A. §136a(c)(1)(D) (West 1980 & West Supp. 1984). The last two categories require an original data submitter to release data for use by a competitor if a compensation figure is established and paid. The data must be released regardless of the fact that the data was submitted under the trade secret protection of prior law.

A very direct way that the 1978 FIFRA Amendments affect producers is by the changes it created in the data compensation system. Under former law, if the parties could not agree on compensation, the EPA Administrator would determine the amount and method of payment. If the original data submitter did not agree with this determination, he could appeal to a federal district court for full judicial review. Pub. L. No. 94-140, §12, 89 Stat. 751, 755 (1975). The 1978 amendments provide that if the parties cannot agree on a compensation figure, the dispute will be settled through binding arbitration by the Federal Mediation and Conciliation Service. Congress has set down no standards which the arbitrator is to use in fixing the amount of compensation. Also the mandatory arbitration

scheme has virtually no provision for judicial review. The statute has stripped the courts of their traditional scope of judicial review by limiting review to cases of fraud, misrepresentation or misconduct by a party or the arbitrator. 7 U.S.C.A. §136a(c)(1)(D) (West 1980 and West Supp. 1984). An applicant submitting test data may submit the data directly or may rely on data appearing in public litterature or on data that has previously been submitted to the agency by a prior applicant. An applicant who does not wish to expend the time and money necessary to create original data may rely on data already developed by another. The original data developer has no choice but to agree on a price or submit to a forced sale of his data.

There is no longer any real protection for the formerly confidential information devoloped through the enormous investment of the original data submitter. It is true that the statute grants a 10-year period of "exclusive use" to the developer of new active ingredients or to one who develops a new use for a previously registered pesticide. However, this does nothing to protect from disclosure the data concerning toxicology, metabolism, environmental chemistry, efficacy and crop safety that have been submitted to EPA. Neither does it prevent lab procedures for obtaining such data from falling into the hands of competitors.

Neither can the data developer rely on patent protection to protect the investment in research and development. Patent protection lasts for a period of seventeen years. 35 U.S.C.A. §§1-376 (West 1984). A patent provides that during the seventeen-year period commencing with the issuance of the patent no one other than the patent's owner can "practice" the invention without the owner's permission. *Id.;* S. Rep. No. 334, 95th Cong., 1st

Sess. 36 (1977). A patent may be issued to cover a newly discovered chemical, a newly discovered use for a previously registered chemical, or a new method for producing the chemical. 35 U.S.C.A. §§1-376 (West 1984).

There are two significant reasons why the patent system may be inadequate to protect incentives for innovation. First, some discoveries are unpatentable because they do not meet the statutory requirement of being new, novel, and nonobvious. McGarity and Shapiro at 850. For example, pesticide innovations lack patent protection if they are composed of active ingredients that were known to kill pests before the attempt to patent them. *Id.*, citing Federal Insecticide, Fungicide, and Rodenticide Act: Hearings before the House Comm. on Agriculture, 95th Cong., 1st Sess. 321-22 (1977) (Statement of John E. Donalds, Dow Chemicals, U.S.A.). As well, data generated during the production and testing of a pesticide are not patentable. Producers try to maintain the data concerning test procedures and test results secret. Companies maintain their research and test data under lock and key and employees are permitted access only on a "need-to-know" basis. Security guards are often deployed around the clock to protect this highly valuable information. Brief of Appellee at 26, *Ruckelshaus v. Monsanto,* 467 U.S. ....., 104 S.Ct. 2862 (1984). *See also* Gannon, *FIFRA and the "Taking" of Trade Secrets,* 8 B.C. Envtl. Aff. L. Rev. 593, 594 (1980).

The extent of protection that the patent laws provide is also affected by the fact that actual protection can be shorter than the prescribed seventeen-year period. Developers of new chemicals or new pesticidal uses normally make prompt applications for patents to avoid the possibility of loss of rights through publication or independent invention by another. In the case of pesticide chemicals,

the patent normally issues well before the developer has established, through long-term testing, that the chemical is safe and effective enough to be registered under FIFRA. S. Rep. No. 334, 95th Cong., 1st Sess. 36 (1977). Six or more years of the seventeen allowed under patent law could elapse before the product is ever put on the market. *Id.; Monsanto* Joint Appendix at 171. After the seventeen-year period expires, the patent laws provide no further protection. The safety and efficacy data could be submitted by a competitor in support of an application to a regulatory agency for approval of an equivalent product. McGarity and Shapiro at 849. Because these firms often do not maintain research operations or have other cost advantages over the firms who do, they could in many cases undersell the original developer. In light of the time and expense of testing, this would deprive an innovater of substantial lead time and impose a significant cost disadvantage. All of this could significantly cut into the return on the investment dollar. Unless a constitutional compensation system is established, investors will be discouraged from taking the financial risk necessary to promote innovation in the pesticide industry.

III

UNLESS A CONSTITUTIONAL COMPENSATION SYSTEM IS ESTABLISHED, COMPANIES WILL BE DISCOURAGED FROM TAKING THE FINANCIAL RISK NECESSARY TO PROMOTE INNOVATION IN THE PESTICIDE INDUSTRY.

The only sure way for a company not to disclose trade secrets is not to market the products at all. Statutory protection afforded by patent law and FIFRA's "exclusive use" provisions do not prevent disclosure of all valuable information submitted to the agency.

Considerable damage is done to the research and development investment of the original data submitter when data submitted to the agency are disclosed to a competitor. Disclosure of health and safety testing data provide competitors with insights concerning their own research in similar areas for related products and imitation pesticides. Such insights could lead to a breakthrough that would undermine the ability of the original innovator to reap the benefits of its innovation. F. Dworkin, Impact of Disclosure of Safety and Efficacy Data on Expenditures for Pharmaceutical Research and Development 12 (April, 1978) (Staff Paper, Economic Analysis Group, FDA Office of Planning and Evaluation). Thus, the technological ability of competitors is considerably increased without a corresponding expenditure of years and millions of dollars in product research and development.

Companies face disclosure of their valuable data with great apprehension:

> [T]he companies fear that competitors will be able to enter the marketplace at lower startup costs since they do not have to produce data to support registrations. The companies also fear that rivals who gain access to the safety and efficacy data will be able to derive other benefits from them which will reduce the producers' competitive advantage. Specifically, the data are also valuable for meeting state or foreign registration requirements, defining and recording advertising and warranty claims, defending against product liability actions, providing leads for product development and improvement, and for discovering cost efficient manufacturing and research methodology and other spin-off technology as well. Gannon, *FIFRA and the "Taking" of Trade Secrets,* 8 B.C. Envtl. Aff. L. Rev. 593, 605 (1980).

The ability of a company to recover its investment would be quickly destroyed if its rival were furnished the trade secret data on any one of the few products a successful company relies upon to recoup its research and development expenditures. This "free ride" would allow such producers an artificial cost advantage at the expense of a company that invested in research and development.

The most important of the property rights afforded company secrets is the right to prevent unauthorized use or disclosure of information. *Underwater Storage, Inc. v. United States Rubber Company,* 371 F.2d 950, 954 (D.C. Cir. 1966), *cert. denied,* 386 U.S. 911 (1967). Once disclosed, all trade secret rights are forever forfeited. *Fisher Stoves v. All Nighter Stove Works, Inc.,* 626 F.2d 193, 196 (1st Cir. 1980); *Harrington v. National Outdoor Advertising Company,* 355 Mo. 524, 196 S.W.2d 786, 791 (1946). The FIFRA provisions cause a transfer of the value of and right to use data to others, particularly competitors, and do so with no standards for setting the amount of compensation and with virtually no judicial review. Such appropriation of data must not be sustained unless a constitutional system of compensation is provided.

It has been suggested that the compensation scheme established by the 1978 FIFRA amendments is necessary to promote competition within the pesticide industry. However, it is recognized that vigorous competition already exists in the pesticide market. *See Monsanto v. Acting Administrator,* 564 F. Supp. 552 (E.D. Mo. 1983); *see also* Gannon, *FIFRA and the "Taking" of Trade Secrets,* 8 B.C. Envtl. Aff. L. Rev. 593 (1980). Rather than helping competition, releasing information could *hurt* competition. It would reduce competition in innovation by eliminating the incentive to invest in costly research and testing. In fact, by permitting a "free ride" it would actually cause market failure. J. Hirschleifer, *Price Theory and Applications* 451 (1976). EPA regulations have already damaged competition. Some firms have left the pesticide research and development field in recent years. Other firms have consolidated—perhaps in part to help spread the cost of research and development and registration of new pesticides. S. Rep. No. 334, 95th Cong., 1st Sess. 51 (1977).

The lack of standards and meaningful judicial review on the compensation issue could result in firms shifting resources away from research and development and into activities offering more promising rates of return, as economists have noted as happening in the drug industry. Grabowski, Vernon & Thomas, *The Effects of Regulatory Policy and the Incentives to Innovate: An International Comparative Analysis,* in Impact of Public Policy on Drug Innovation and Pricing 47, 53 (S. Mitchell and E. Link, eds. 1976).

Few would stand to profit from cutbacks in the pesticide industry. Loss of improvement and innovation would be the result. Pesticides are used world-wide to control destructive plants and animals and are partially responsible for greater crop production, a decreased incidence of debilitating diseases, and generally improved standards of living. *Constitutional Challenges to FIFRA's Use and Disclosure Safeguards Yield Mixed Results,* 11 Envtl. L. Rep. (Envtl. L. Inst.) 10157 (August, 1981). Successful pest control accounts for a substantial portion of the dramatic increase in American farm yields and has resulted in lower food prices for the American consumer. S. Rep. No. 334, 95th Cong., 1st Sess. 32 (1977). Unless the pesticide producers and innovators have reason to believe that they will receive a fair return on their research dollar, cutbacks in development programs are the assured result. Much would be lost if this were allowed to happen.

CONCLUSION

Tremendous amounts of time and financial resources are devoted yearly to research and development of new pesticides. No small part of that investment is spent on preparing the safety and efficacy data on the pesticide necessary for EPA registration. As FIFRA now stands, certain data submitted to EPA in support of pesticide registration may be used by a competitor in support of registration of the competitor's pesticide or for use to improve lab procedures and testing methods. The competitor must compensate the original data developer for use of the data.

The present compensation system provides no standards for determining the compensation figure and allows for virtually no judicial review. Such a system shortens the amount of time necessary to obtain EPA registration. It may also allow the competitor to purchase the data at below market price. Thus the competitor could be given both a time and financial shortcut to the pesticide market. Shortcuts granted to competitors only serve to increase the risk involved in the research and development of new pesticides. Unless companies investing in product development are assured of a constitutional compensation system, with standards and judicial review, cutbacks in research and development are certain. Pesticides are extremely valuable in preventing disease, increasing crop production and reducing the cost of agricultural products. Environmentally safe and effective pesticides are also relied upon to help reduce the amount of chemical pollutants found in the land and water. To keep vitality in new product development investment in research and development must not be discouraged.

For these reasons, amicus respectfully requests this court to affirm the ruling of the lower court.

Respectfully submitted,

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